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Bob Goldstein  
Vice President of Production  
Hodgson Mill  
1203 Niccum Avenue  
Effingham, Illinois 62401

Re: Docket Nos. 01P-0290/PRC 1 and 01P-0290/CP 2

Dear Mr. Goldstein:

This letter is in response to your petition for reconsideration (01P-0290/PRC 1), dated January 20, 2003, requesting that the Food and Drug Administration (FDA) reconsider its July 9, 2002 decision to deny your June 18, 2001 petition to establish a standard of identity for the term "stone ground" as applied to wheat flour. This letter also responds to your citizen petition (01P-0290/CP 2), dated January 20, 2003, proposing a standard for "stone ground" and supported by a recent consumer survey.

FDA denied your previously submitted citizen petition on July 9, 2002. In its response, FDA stated that your June 18, 2001 petition did not provide any data to show what consumers understand the term "stone ground" to mean and to show that consumers are buying a product labeled "stone ground" that differs from their expectations. FDA also stated that in the absence of any substantiating data or other information, your June 18, 2001 petition failed to demonstrate that your proposed standard for "stone ground" would promote honesty and fair dealing in the interest of consumers and, therefore, FDA denied that petition.

In your citizen petition, dated January 20, 2003, you presented new information about a consumer survey conducted to support your petition and, in light of this consumer survey information, you requested FDA to reconsider establishing a standard of identity for the term "stone ground" as applied to wheat flour. Your petition for reconsideration requested similar relief.

Although your petition for reconsideration was filed after the 30-day deadline established by Title 21 Code of Federal Regulations (CFR) 10.33(b), we considered the merits of that petition as we evaluated the January 20, 2003, citizen petition. In accordance with 21 CFR 10.30(e)(3), this letter is to advise you that FDA is denying, without prejudice, your petition for reconsideration (01P-0290/PRC 1) and your citizen petition (01P-0290/CP 2).

Section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341) authorizes FDA, by delegation from the Secretary of Health and Human Services, to establish a standard of identity for a food to promote honesty and fair dealing in the interest of consumers. We have carefully reviewed the consumer survey information that you presented to support your petitions and have

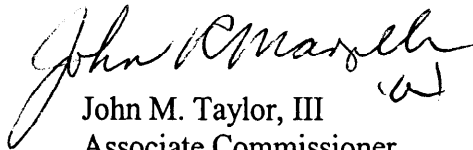
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determined that the survey data fail to provide convincing evidence that a standard of identity for “stone ground” as applied to wheat flour is necessary to promote honesty and fair dealing in the interest of consumers. The consumer survey information you have provided is incomplete. Although some data were presented, no information was provided as to how these data were acquired. Also, neither petition provides any information about the characteristics of the sample (e.g., gender, age, education, etc.) or how the participants were recruited into the study. Therefore, the results reported cannot be generalized to the general public or any other defined subgroup. The survey results also do not provide a clear understanding of consumers’ expectations or beliefs about the term “stone ground” as applied to wheat flour. In addition, the set of questions included in the survey do not demonstrate that the current use of the term “stone ground” on labeling is important to consumers or that it is used to make product choices.

Therefore, you have thus far provided no substantiating data or information to demonstrate that your proposed standard for “stone ground” would promote honesty and fair dealing in the interest of consumers, as required by 21 U.S.C. 341. Accordingly, we are denying your petition for reconsideration and your citizen petition for a standard of identity for “stone ground” as applied to wheat flour.

Sincerely yours,



John M. Taylor, III  
Associate Commissioner  
for Regulatory Affairs